DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
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Denver, Colorado 80225-0087
Telephone: 303-236-3000
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February 23, 2001

WARNING LETTER

PURGED

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jeffrey G. McBride
President
Schryver Medical Sales & Marketing, Inc.
4959 Kingston Street
Denver, CO 80239

Ref. # DEN- 01-21

Dear Mr. McBride:

During an inspection of your firm, Schryver Medical Sales & Marketing, Inc., Denver, Colorado, on January 24 & 25, 2001, Consumer Safety Officer Linda M. Cherry determined that your firm distributes gas and liquid Medical Oxygen U.S.P. to long term care homes. Medical Oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your liquid Oxygen, U.S.P., is adulterated under section 501(a)(2)(B) of the Act in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations (GMPs) under Title 21, Code of Federal Regulations, parts 210 and 211 (21 CFR 210 and 211). Deviations noted during the inspection include, but are not limited to the following:

1. Failure to adequately test Oxygen, U.S.P., for identity and purity as required by 21 CFR 211.165(a). Specifically, your firm fails to test the incoming Oxygen U.S.P. by one of the following methods: 1) have an individual who has received training specific to the analytical methodology witness (and document) the testing; 2) rely on a valid Certificate of Analysis from the supplier along with performing an identity test on each fill of the vehicle-mounted vessel with liquid Oxygen U.S.P.; or perform the full U.S.P. testing.

2. Failure to retest at least for identity, the contents of cryogenic home vessels serviced or repaired, prior to redistribution to customers as required by 21 CFR 211.87.

3. Failure to perform adequate prefill operations on cryogenic home vessels prior to filling as required by 21 CFR 211.84(d)(3)

4. Failure to establish complete written procedures designed to assure that correct labels and labeling are used, as required by 21 CFR 211.130. For example, your written procedure for labeling does not identify or contain examples of the current and approved labels; nor are lot numbers assigned to cryogenic home vessels filled at your facility.

5. Failure to document the review of daily fill records and analytical results (CAO's) the assure compliance with all established, approved written procedures as required by 21 CFR 211.192.

Review of labeling used on cylinders of compressed medical oxygen filled by your firm reveals the products are also misbranded with the meaning of Section 502(b)(2) of the Act in that labeling fails to contain a statement of the quantity of contents as required by 21 CFR 201.51. With respect to this violation, the contents of cylinders may be expressed in terms of the available volume of Oxygen U.S.P. in liters at 70° F (21.1° C) and one (1) atmosphere.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. At the conclusion of the inspection, Investigator Cherry advised you of additional deficiencies in your written procedures and documentation practices in several areas including testing, quarantine, training and calibration. As president, it is your responsibility to assure adherence with all requirements of the Act and Good Manufacturing Practice Regulations.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Food, Drug and Cosmetic Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason

why the corrective action is not completed within the response time and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to H. Tom Warwick, Compliance Officer, at the above address.

Sincerely,

Thomas A. Allison
District Director

cc:
Mr. Adam Trujillo, Regional Administrator
Health Care Financing Administration, DHHS Region VIII
1600 Broadway, Suite 700
Denver, Colorado 80202-4967